Quality Improvement and Tissue-Type Plasminogen Activator for Acute Ischemic Stroke
A Cleveland Update

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Background and Purpose—A systematic audit of intravenous tissue-type plasminogen activator (tPA) use and stroke outcomes in Cleveland, Ohio, during 1997–1998 demonstrated higher rates of symptomatic intracranial hemorrhage (ICH) than reported in the National Institute of Neurological Disorders and Stroke (NINDS) trial. We now report updated results of intravenous tPA use in the Cleveland Clinic Health System (CCHS).

Methods—A stroke quality improvement program was initiated in the 9-hospital CCHS in 1999. A retrospective chart review for all stroke patients with primary International Classification of Diseases, Ninth Revision, Clinical Modification diagnosis codes 434 and 436 admitted to the 9 hospitals from June 1999 to June 2000 was used to determine outcomes of patients treated with intravenous tPA.

Results—Intravenous tPA was given to 18.8% of patients arriving within 3 hours of symptom onset. Protocol deviations occurred in 19.1% of patients given intravenous tPA. The symptomatic ICH rate was 6.4%.

Conclusions—Since 1997, intravenous tPA use has increased, while the rates of symptomatic ICH and protocol deviations have decreased in the CCHS. The CCHS symptomatic ICH rate is now similar to that reported in the NINDS trial. These improvements occurred after initiation of a stroke quality improvement program. (Stroke. 2003;34:799-800.)

Key Words: cerebral infarction ■ quality of health care ■ thrombolytic therapy

There is continuing controversy over the safety and effectiveness of intravenous tissue-type plasminogen activator (tPA) for acute stroke outside of the clinical trial setting. Phase IV studies involving experienced stroke centers found rates of symptomatic intracranial hemorrhage (ICH) similar to the 6.4% seen in the National Institute of Neurological Disorders and Stroke (NINDS) trial. However, in a systematic audit of intravenous tPA use in 29 hospitals in greater Cleveland, Ohio, during 1997–1998, the rate of symptomatic ICH was 15.7% (95% CI, 8.1% to 26.4%). Protocol deviations occurred in 50% of intravenous tPA cases, suggesting that nonadherence to national guidelines contributed to the outcomes. The Cleveland study has been used by some to vigorously discourage the use of intravenous tPA, at least at the community hospital level.

The Cleveland Clinic Health System (CCHS) comprises 8 community and 1 tertiary hospital and represents 31% (9/29) of the hospitals included in the original audit. In the 1997–1998 Cleveland audit of intravenous tPA, the CCHS gave intravenous tPA to 1.8% of ischemic stroke patients and had a 13.8% rate of symptomatic ICH and a 31.0% rate of protocol deviations. The CCHS rates were not significantly different from the citywide rates. Because of the results of the first audit, in 1999 a quality improvement (QI) program was implemented by CCHS to reduce the rate of hemorrhagic complications and to increase patient access to intravenous tPA. We now report updated intravenous tPA outcomes data for the 9-hospital system.

Subjects and Methods
The study was approved by the Cleveland Clinic Foundation Institutional Review Board.

A retrospective chart review was performed by trained data abstractors on patients admitted to the 9 CCHS hospitals from June 15, 2000, through June 15, 2001, with a primary discharge diagnosis of stroke (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] codes 433.x1, 434.x1, 436.xx, 997.02). The medical records of stroke patients arriving within 3 hours were then reviewed by a neurologist using a standardized template. Information collected included National Institutes of Health Stroke Scale (NIHSS) scores and compliance with national treatment guidelines.

To allow comparison with the previous Cleveland audit, rates of intravenous tPA use were calculated among all ischemic stroke patients.
patients with the primary ICD-9-CM codes 434 and 436 and among the subgroup arriving within 3 hours of symptom onset.

**QI Program**

The CCHS stroke and emergency medicine committees implemented a stroke QI plan in January 1999. The CCHS stroke QI team meets quarterly to review data and facilitate QI initiatives. A standardized “dashboard” report is provided that lists the performance of CCHS hospitals individually and collectively for the system. Best practices are benchmarked within the system and compared with national evidence-based guidelines. Hospital action plans are reviewed periodically by the Stroke and Emergency Medicine Committees and the Medical Operations Council. All CCHS hospitals were expected to have an acute stroke protocol in the emergency department, and a 24-hour CCHS stroke beeper was in place daily. Lastly, there are frequent continuing medical education programs related to acute stroke care and use of intravenous tPA.

**Results**

Among the 1923 CCHS patients hospitalized for ischemic stroke in the 1-year period of the study, only 288 ischemic stroke patients arrived within 3 hours of symptom onset (14.9%). Medical records were available for review in 227 of these patients, including all patients who received intravenous tPA.

Intravenous tPA was administered to 47 patients, which represents 2.7% (47/1727) of all ischemic stroke patients and 18.8% (47/250) of ischemic stroke patients arriving within 3 hours. Hospitals gave intravenous tPA to a median of 4 patients over the 1-year period (range, 1 to 13 patients).

Symptomatic ICH, defined as hemorrhage resulting in neurological worsening occurring within 48 hours, occurred in 3 patients receiving intravenous tPA (6.4%; 95% CI, 0% to 13.4%), all of which were fatal. The combined rate of patients with treatment beyond 3 hours (n=7), anticoagulation within 24 hours (n=1), and deviations from blood pressure guidelines (n=3) was 17.0% (8/47; 95% CI, 6.3% to 27.7%). One additional patient with a minor deficit (NIHSS score=3) received intravenous tPA, resulting in an overall protocol deviation rate of 19.1% (9/47; 95% CI, 7.9% to 30.3%).

**Discussion**

Two years after the initial Cleveland audit, the rate of symptomatic ICH with intravenous tPA dropped from 13.4% to 6.4% in the 9 CCHS hospitals. During this same time period, the rate of 3 specified protocol deviations declined from 33% to 17.0%, and the intravenous tPA usage rate increased from 1.8% to 2.7% among all patients with ischemic stroke.

A strength of the previously reported systematic Cleveland intravenous tPA audit was the regional nature of the data collection. However, the small number of stroke patients treated with intravenous tPA in Cleveland resulted in wide CIs around the symptomatic ICH rate. The limited documentation of baseline NIHSS scores, available in only 40% of intravenous tPA patients, may have resulted in inadequate adjustment for baseline characteristics of stroke patients who did and did not receive intravenous tPA. Nonetheless, the first Cleveland intravenous tPA audit raised concerns about the effectiveness and safety of intravenous tPA for acute stroke in the community.

There are several possible explanations for the improvement seen in the safety of intravenous tPA within the health system in the 2 years since the initial report. The improved results may have been due to chance. They may also reflect undetected changes in patient characteristics such as stroke severity. More likely, experience with intravenous tPA and better familiarity with practice guidelines probably played a role in the reduced rates of protocol deviations and symptomatic ICH. Grotta and colleagues found that, even among hospitals and physicians with clinical trial experience with intravenous tPA, the rates of symptomatic ICH declined from 1996 to 2000. The adoption of intravenous tPA use for stroke may mimic the gradual rates of acceptance observed when thrombolytic therapy for myocardial infarction was introduced. Lastly, there is a high likelihood that our stroke QI program influenced the use and safety of intravenous tPA in our hospital system, as has been demonstrated with thrombolytic therapy for myocardial infarction. Our results suggest that intravenous tPA can be given safely to appropriate stroke patients at the community hospital level and that community physician performance improves over time.

**References**

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